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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-418F]

Final Adjusted Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the final adjusted 2015 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended.

21 U.S.C. 801–971. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purposes of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Section 306 of the CSA (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA. 28 CFR 0.100(b).

Background

The DEA established the initial 2015 aggregate production quotas for controlled substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on September 8, 2014. 79 FR 53216. That notice stated that the DEA could adjust, as needed, the established aggregate production quotas and assessment of annual needs in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The proposed adjusted 2015 aggregate production quotas for controlled substances in schedules I and II and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently

published in the *Federal Register* on July 8, 2015, 80 FR 39156, in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted 2015 aggregate production quotas and assessment of annual needs on or before August 7, 2015.

Analysis for Final Adjusted 2015 Aggregate Production Quotas and Assessment of Annual Needs

Consideration has been given to the criteria outlined in the July 8, 2015, notice of proposed adjusted aggregate production quotas and assessment of annual needs, 80 FR 39156, in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. Five companies submitted timely comments regarding twelve schedule I and II controlled substances. These comments suggested that the proposed adjusted aggregate production quotas for codeine (for sale), fentanyl, gamma hydroxybutric acid, hydrocodone (for sale), methadone, methadone intermediate, methylphenidate, morphine (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), and oxymorphone (for sale) were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements, and for the establishment and maintenance of reserve stocks. The DEA did not receive any comments related to the proposal not to adjust the 2015 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine.

In accordance with 21 CFR 1303.13, the DEA has taken into consideration the above comments along with the relevant 2014 year-end inventories, initial 2015 manufacturing and import quotas, 2015 export requirements, actual and projected 2015 sales, research and product development requirements, and the additional quota applications received.

Upon consideration of the above, the Administrator determined that the proposed adjusted 2015 aggregate production quotas for dihydroetorphine, ethylmorphine, etorphine HCl, racemethorphan, racemorphan, methylphenidate, and oxycodone (for sale) required additional consideration and hereby further adjusts the proposed 2015 aggregate production quotas for these substances. Regarding codeine (for sale), fentanyl, gamma hydroxybutric acid, hydrocodone (for sale), methadone, methadone intermediate, morphine (for conversion), oripavine, oxymorphone (for conversion), and oxymorphone (for sale) the Administrator hereby determines that the proposed adjusted 2015 aggregate production quotas for these substances as published in the *Federal Register* on July 8, 2015, 80 FR 39156, are sufficient to meet the current 2015 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate reserve stock.

As described in the previously published notice establishing the 2015 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. *See* 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA included in all schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The final established aggregate production quotas will

reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

Pursuant to the above, the Administrator hereby finalizes the 2015 aggregate production quotas for the following schedule I and II controlled substances and the 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Final Adjusted 2015 Quotas (g)
Schedule I	
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	25
[1-(5-Fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	25
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	25
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	25
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45

1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	15
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-n-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	25
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	50
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-Fluoro-N-methylcathinone (3-FMC)	25
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Fluoro-N-methylcathinone (4-FMC)	25

4-Methoxyamphetamine	100
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-ethylcathinone (4-MEC)	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl- α -pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
Acetyl-alpha-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
alpha-Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α -PBP)	25
alpha-Pyrrolidinopentiophenone (α -PVP)	25
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
Betameprodine	2
Betamethadol	4
Betaprodine	2
Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine-N-oxide	305
Desomorphine	25
Diethyltryptamine	25

Difenoxin	11,000
Dihydromorphine	3,990,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylamine	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	50
Hydromorphanol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	658,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	350
N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA)	15
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA)	15
N,N-Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	25
N-Benzylpiperazine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	40

Para-fluorofentanyl	5
Parahexyl	5
Phenomorphan	2
Pholcodine	5
Psilocybin	30
Psilocyn	30
Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	25
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	25
Tetrahydrocannabinols	511,250
Thiofentanyl	2
Tilidine	25
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	21,875,000
Amphetamine (for sale)	37,500,000
Carfentanil	19
Cocaine	275,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	63,900,000
Dextropropoxyphene	45
Dihydrocodeine	226,375
Dihydroetorphine	3
Diphenoxylate (for conversion)	75,000
Diphenoxylate (for sale)	1,337,500
Ecgonine	174,375
Ethylmorphine	5
Etorphine hydrochloride	3
Fentanyl	2,300,000
Glutethimide	3
Hydrocodone (for conversion)	137,500
Hydrocodone (for sale)	99,625,000
Hydromorphone	7,000,000
Isomethadone	5

Levo-alphaacetylmethadol (LAAM)	4
Levomethorphan	30
Levorphanol	7,125
Lisdexamfetamine	29,750,000
Meperidine	6,250,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	32
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	34,375,000
Methamphetamine	2,061,375
[1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	96,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,750
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,475,000
Opium (powder)	112,500
Opium (tincture)	687,500
Oripavine	35,000,000
Oxycodone (for conversion)	8,350,000
Oxycodone (for sale)	141,375,000
Oxymorphone (for conversion)	29,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	38
Phenmetrazine	3
Phenylacetone	9,375,000
Racemethorphan	5
Racemorphan	3
Remifentanil	4,200
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	12,500,000

Thebaine	125,000,000
List I Chemicals	
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

Aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

Dated: September 10, 2015.

Chuck Rosenberg,
Acting Administrator.

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